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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/674,337 | 07/26/2001 | Satoshi Mori | 55107 | 5232 |

21874 7590 04/06/2004
EDWARDS & ANGELL, LLP
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BOSTON, MA 02205

EXAMINER

FRONDA, CHRISTIAN L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,337

Applicant(s)

MORI ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/11/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/30/2000.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 12/29/2003 has been entered.

2. Claims 1-4 and 6 are under consideration in this Office Action.

Nucleotide and/or Amino Acid Sequence Disclosures

3. No specific SEQ ID NOs have been assigned to the amino acid sequences listed as (1) - (6) in claim 1. It should be noted that SEQ ID NO: 1 is disclosed in the sequence listing as an amino acid sequence without any X amino acid residues cited.

Thus, the application clearly fails to comply with requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).

Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 C.F.R. 1.821(e), 1.821(f), 1.821(g), 1.825(b), 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the Patent and Trademark Office, such request in accordance with 37 C.F.R. 1.821(e) may be submitted in lieu of a new CRF. See MPEP § 2420.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1; does not reasonably provide enablement for a nicotianamine synthase having 50% identity to SEQ ID NO: 1 and comprising at least one of amino acid sequences (1)-(6).

Applicants' arguments filed 3/11/2004 have been fully considered but they are not persuasive. Applicants' position is that the specification provides assays to screen and search for the claimed invention and provided an alignment shown in FIG. 7 for several nicotianamine synthases. The Examiner disagrees for the reasons of record and the reasons stated below.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed nicotianamine synthase having more than 50% identity to SEQ ID NO: 1 is undue. SEQ ID NO: 1 is disclosed by the specification as an amino acid sequence of 328 amino acid residues. The claims require at least 50% of SEQ ID NO: 1 to be altered where at least 164 amino acid residues are changed (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1. One of ordinary skill in the art would have to screen and search for proteins having the changes in the amino acid sequence and then determine by enzymatic assays whether the protein has nicotianamine synthase activity. Such screening and searching is outside the scope of routine experimentation.

Limiting the claims to recite the specific amino acid sequences of (1)-(6) does not overcome the rejection since no more than 32 amino acid residues out of a total of 164 amino acid residues as encompassed by the 50% identity limitation to SEQ ID NO: 1 are accounted for which must be conserved in order to preserve nicotianamine synthase activity. Furthermore, the specification does not disclose that a region found to be conserved throughout several nicotianamine synthases as suggested by amino acid alignments is an indication that the said region is invariant and must be retained for any enzyme activity. Teaching regarding searching or screening for the claimed invention is not teaching for making the claimed nicotianamine synthase.

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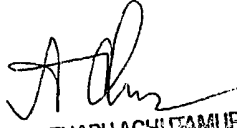
Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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SUPERVISORY PATENT EXAMINER
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